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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,789	11/29/2001	Taiichiroh Meguro	049400-5021	9139

9629 7590 02/13/2003

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,789

Applicant(s)

MEGURO ET AL.

CA

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 - 8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Specification

1. The disclosure is objected to because of the following informalities: Page 1, paragraph 3 recites, "a tubular balloon catheter are introduced."; the same reference numeral (3a) is used to describe both a "head portion" (Page 7, paragraph 7) and a "helical spring" (Page 12, paragraph 2; Page 13, paragraph 2); the last paragraph on page 14 states, "mire finish"; the same reference numeral (21) is used to describe both "carves" (Page 15, paragraph 2) and "helical spring" (Page 15, paragraph 3). Additionally, "carves" are referred to with reference numeral (12) in paragraph 2, Page 17.

Appropriate correction is required.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "3a" has been used to designate both a "helical spring" and "head portion". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 6 is objected to because of the following informalities: line 3 states, "which fit into". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to claim 7, it is unclear what is meant by, "a magnitude of which is determined enough to provisionally connect said balloon catheter to said front catheter engagement portion" in lines 5 –7.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 4,413,989 to Schjeldahl et al.

In reference to claim 1, Schjeldahl et al. discloses a medical guide wire (36) comprising: an elongated and flexible core member (Col. 7, lines 7 – 36); a front catheter engagement portion (42) provided around the core member and formed into a bulged shape or a truncated cone shape (Col. 7, lines 48 – 68), a diameter of which progressively decreases as approaching a rear end of the front catheter engagement portion; the front catheter engagement portion being capped with a balloon catheter (Figure 2) to provisionally connect the balloon catheter so that the balloon catheter is inserted into a blood vessel concurrently at the time when introducing a medical guide wire into the blood vessel.

In reference to claim 2, Schjeldahl et al. discloses a leading bulge portion being formed by an ellipsoidal helical spring or columnar member (42), and a rear half of the leading bulge portion

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forming the front catheter engagement portion so as to introduce the leading bulge portion into a stricture blood vessel area.

In reference to claim 4, Schjeldahl et al. discloses a provisionally connecting member (26) being provided at a front open end of the balloon catheter to provisionally connect the balloon catheter to the front catheter engagement portion (Col. 6, lines 29 – 39).

In reference to claims 7 and 8, Schjeldahl et al. discloses the balloon catheter and the front catheter engagement portion being formed by a common synthetic resin selected from the group consisting of polyamide, polyvinyl chloride, polytetrafluoroethylene and polyethylene that inherently has a coefficient to static friction therebetween (Col. 6, lines 4 – 6; Col. 7, lines 7 – 36).

8. Claims 1, 2 and 3 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,616,653 to Samson et al.

In reference to claim 1, Samson et al. discloses a medical guide wire comprising: an elongated and flexible core member (Col. 2, lines 51 – 66); a front catheter engagement portion (29) provided around the core member and formed into a bulged shape or a truncated cone shape, a diameter of which progressively decreases as approaching a rear end of the front catheter engagement portion (Figure 2); the front catheter engagement portion being capped with a balloon catheter to provisionally connect the balloon catheter (Col. 2, lines 22 – 33) so that the balloon catheter is inserted into a blood vessel concurrently at the time when introducing a medical guide wire into the blood vessel (Col. 2, lines 1 – 10).

In reference to claim 2, Samson et al. discloses a leading bulge portion being formed by an ellipsoidal helical spring or columnar member (28), and a rear half of the leading bulge (29) portion forming the front catheter engagement portion so as to introduce the leading bulge portion into a stricture blood vessel area (Col. 4, lines 9 – 11).

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In reference to claim 3, Samson et al. discloses the front catheter engagement portion being formed by depositing a solder or an adhesive on the core member (Col. 2, lines 60 – 62).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 2, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,409,470 to McIntyre et al. in view of U.S. Patent No. 6,132,389 to Cornish et al. and further in view of U.S. Patent No. 5,465,733 to Hinohara et al.

In reference to claim 1, McIntyre et al. discloses a medical guide wire comprising: an elongated and flexible core member (Col. 2, lines 59 – 65); a front catheter engagement portion provided around the core member (Col. 2, lines 50 – 55); the front catheter engagement portion being capped with a balloon catheter (Col. 4, lines 28 – 34) to provisionally connect the balloon catheter so that the balloon catheter is inserted into a blood vessel concurrently at the time when introducing a medical guide wire into the blood vessel (Col. 5, lines 10 – 12). However, McIntyre fails to disclose the front catheter engagement portion being formed into a bulged shape or a truncated cone shape, a diameter of which progressively decreases as approaching a rear end of the front catheter engagement portion. Cornish et al. discloses a helical spring (20; Figure 1) that has a bulge and truncated cone shape, a diameter of which progressively decreases as approaching a rear. Hinohara et al. teaches a bulge shape, a diameter of which progressively decreases as approaching a rear (26; Figure 3) for use in making it easier for angioplasty balloons or other therapeutic devices to

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cross a stenosis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the front catheter engagement portion as disclosed by McIntyre et al. to have the shape of the helical spring as taught by Cornish et al. in order to assist the catheter to cross tightly stenotic lesions more easily and to eliminate any step between the guide wire and the catheter tip which could scrape arterial walls (Hinohara et al., Col. 3, lines 56 –61)

In reference to claim 2, McIntyre et al. discloses a leading bulge portion being formed by an ellipsoidal helical spring or columnar member (20), and a rear half of the leading bulge portion forming the front catheter engagement portion (24) so as to introduce the leading bulge portion into a stricture blood vessel area (Col. 3, lines 20 – 24).

In reference to claim 4, McIntyre et al. discloses a provisionally connecting member (Col. 2, lines 50 - 55) being provided at a front open end of the balloon catheter to provisionally connect the balloon catheter to the front catheter engagement portion (Col. 4, lines 28 –34).

In reference to claim 6, McIntyre et al. discloses a groove that fits into the leading bulge portion formed by an ellipsoidal helical spring (Figure 3).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent No. 5,378,236 to Seifert.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization

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where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF

February 9, 2003



**MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**